



Practical urodynamics

Male lower urinary tract symptoms: The role of urodynamics[☆]Jerry G. Blaivas^{a,†}, Johnson F. Tsui^{b,*}^a Department of Urology, Weill Medical College of Cornell University, SUNY Downstate College of Medicine, New York, NY 10075, USA^b Institute for Bladder and Prostate Research, SUNY Downstate College of Medicine, New York, NY 10075, USACME
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1. Introduction

For nearly the entire 20th century, it was believed that lower urinary tract (LUT) symptoms (LUTS) in men were caused by benign prostatic hyperplasia (BPH) which, in turn, caused benign prostatic obstruction (BPO) and that BPH and BPO were synonymous. It is now known that the pathophysiology of LUTS is multifactorial, and that only about two-thirds of men with LUTS have BPO according to urodynamic criteria.^{1–4} LUTS are empirically divided into storage and emptying symptoms. Storage symptoms include urinary frequency, urgency, urge incontinence, nocturia, and bladder/urethral pain. Emptying symptoms are comprised of hesitancy, straining to void, a weak stream, a feeling of incomplete bladder emptying, and urinary retention. Regardless of the symptoms, though, the underlying pathophysiology is limited to five conditions: 1) bladder outlet obstruction (BOO), 2) impaired detrusor contractility (IDC), 3) detrusor overactivity (DO), 4) low bladder compliance (LBC), and 5) sensory urgency (SU).^{1–4} Further, several studies demonstrated a lack of correlation between symptoms and

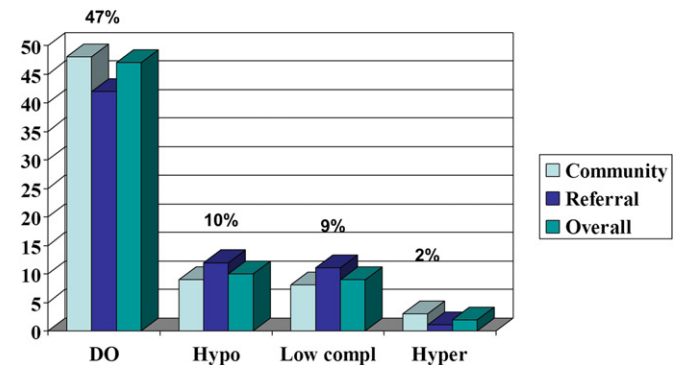
urodynamic data.^{5–8} Accordingly, the only means of assessing the pathophysiology is by urodynamics. Determining the urodynamic abnormalities responsible for LUTS is important so that treatment can be directed at the underlying pathophysiology.

2. Urodynamic techniques

From a clinical standpoint, the purpose of urodynamic testing is to measure and record various physiologic variables while the patient is experiencing those symptoms which constitute his usual complaints. In this context, urodynamics may be considered to be a provocative test of LUT function. Thus, it is the responsibility of the examiner to ensure that the patient's symptoms are, in fact, reproduced during the study. To this end, it is important that the examiner has all relevant clinical information in his/her consciousness as the urodynamic study progresses. Prior to the

Table 1A

Urodynamic diagnosis during bladder filling in unselected men with lower urinary tract symptoms (LUTS) comparing community to referral practice. DO, detrusor overactivity; Hypo, hyposensitive bladder (capacity > 750 mL); Low compl, low bladder compliance (< 20 mL/cmH₂O); Hyper, hypersensitive bladder (bladder capacity < 150 mL) (with permission from Fusco et al. *J Urol* 2001;166:910–3).



Abbreviations: BPH, benign prostatic hyperplasia; BOO, bladder outlet obstruction; BOOI, bladder outlet obstruction index; BPO, benign prostatic obstruction; DO, detrusor overactivity; EMG, electromyogram; FSF, first sensation of filling; IDC, impaired detrusor contractility; IPSS, International Prostate Symptom Score; LBC, low bladder compliance; LUT, lower urinary tract; LUTS, lower urinary tract symptoms; OAB, overactive bladder; pabd, abdominal pressure measured via a rectal catheter; pdet, detrusor pressure – the electronic subtraction of pabd from pves; PdetQmax, detrusor pressure at maximum flow; PFS, pressure-flow study; pves, vesical pressure measured via a transurethral catheter; PVR, post-voided residual volume; Qmax, maximum or peak flow; SU, sensory urgency; TURP, transurethral resection of the prostate; USG, ultrasonography.

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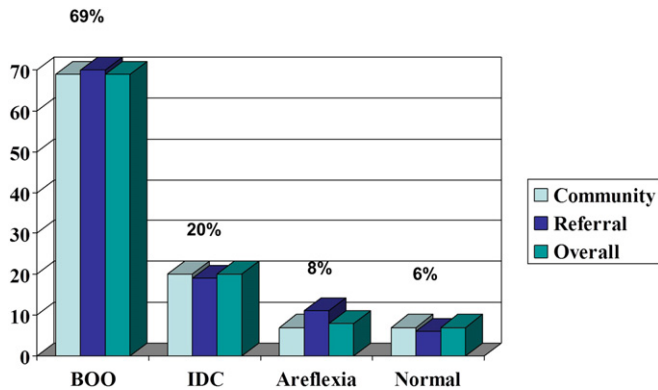
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Table 1B

Urodynamic diagnosis during voiding in unselected men with LUTS comparing community to referral practice. BOO, bladder outlet obstruction; IDC, impaired detrusor contractility; Areflexia, acontractile bladder (with permission from Fusco et al. *J Urol* 2001;166:910-3).



study, the patient should have undergone a fairly extensive evaluation including: 1) focused history and physical examination, 2) urinalysis +/- culture, 3) bladder diary, 4) pad test (for patients with incontinence), 5) uroflow, and 6) post-voiding residual (PVR) urine. In order to interpret urodynamic studies properly, the following

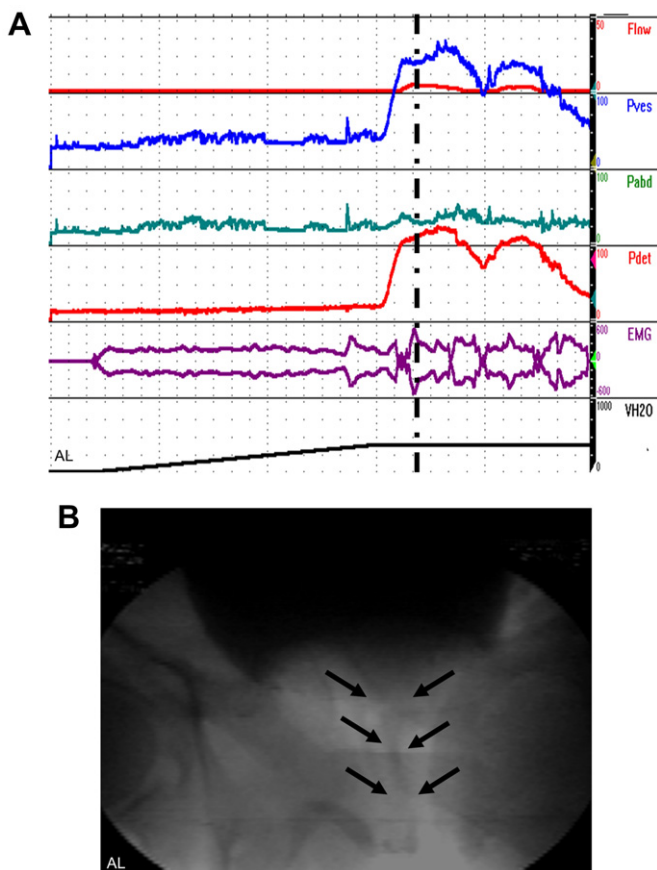


Fig. 1. Schaefer grade 5 prostatic obstruction in a 63-year-old man who developed urinary retention and was treated with an indwelling catheter and tamsulosin for 5 days, at which time this urodynamic study was conducted. A. Urodynamic tracing. At a bladder volume of approximately 400 mL, he had a voluntary detrusor contraction. $Q_{max} = 5$ mL/s, $P_{det@Q_{max}} = 117$ cmH₂O (vertical line), BOOI = 107; voided volume = 215 mL, post-void residual = 174 mL. This corresponds to grade 5 obstruction on the Schafer nomogram. B. X-ray obtained at Q_{max} (vertical line, Fig. 10A) reveals the prostatic urethra to be elongated and barely visible. He underwent KTP laser ablation of the prostate and his AUA symptom score was 6 one year postoperatively.

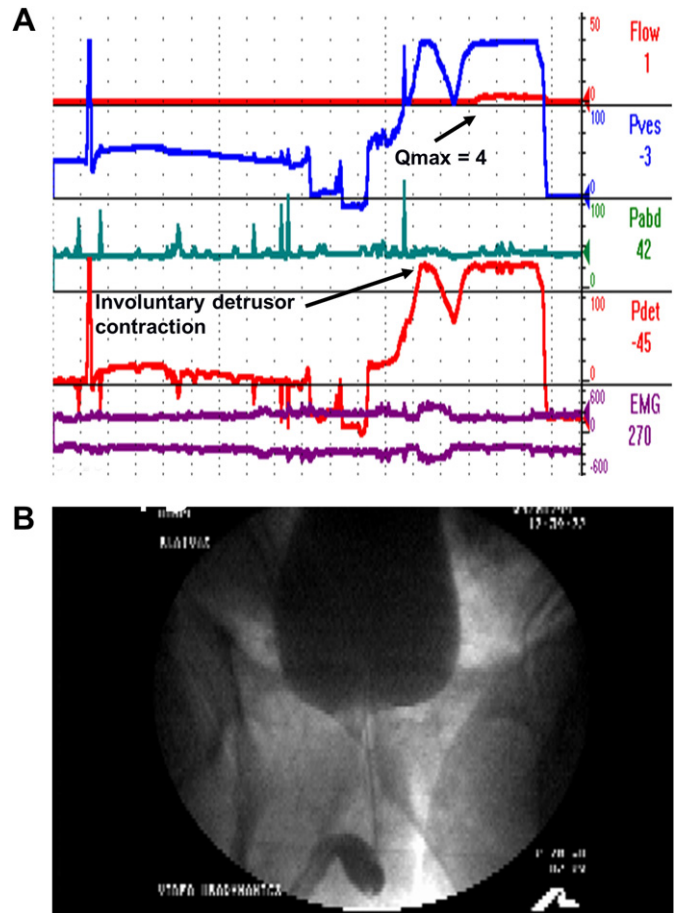


Fig. 2. Schafer grade 6 obstruction and type 3 overactive bladder (OAB) in a 56-year-old man with a 10-year history of severe OAB and obstructive symptoms treated with doxazosin and finasteride, AUASS = 27. A. Urodynamic tracing. He had an involuntary detrusor contraction at a bladder volume of 175 mL and was able to temporarily prevent incontinence by contracting his sphincter, but was unable to abort the detrusor contraction and finally voided involuntarily with a sustained detrusor contraction. $P_{det@Q_{max}} = 135$ cmH₂O; $Q_{max} = 4$ mL/s, BOOI = 127. The sudden fall in vesical pressure (pves) and a negative detrusor pressure at maximum flow (pdet) were artifacts caused by the catheter moving into the urethra. It was replaced, and the pressure recording was accurate again. B. X-ray obtained at Q_{max} showing a diffusely narrowed prostatic urethra. He underwent a suprapubic prostatectomy (350 g prostate), and his urinary frequency decreased from 18 to eight voids per day, his urgency subsided, maximum voided volume increased from 120 to 240 mL, Q_{max} increased from 4 to 17 mL/s, and the post-void residual decreased from 68 to 8 mL.

information should be available to the examiner before the start of the study:

- 1) What symptoms are you trying to reproduce?;
- 2) What is the functional bladder capacity (maximum voided volume on the voiding diary)?;
- 3) What is the PVR urine?;
- 4) What is the uroflow?; and
- 5) Is there a neurologic disorder that could be causing the neurogenic bladder?

To evaluate male LUTS (excluding stress incontinence), urodynamics is comprised of the following procedures: cystometry, uroflow, sphincter electromyography (EMG), pressure/flow, and radiographic visualization of the LUT. Each may be performed alone or synchronously with one another. When done synchronously, it is called multichannel urodynamics; when performed with fluoroscopic visualization of the LUT, it is called video-urodynamics. As a general rule, uroflow and PVR are usually

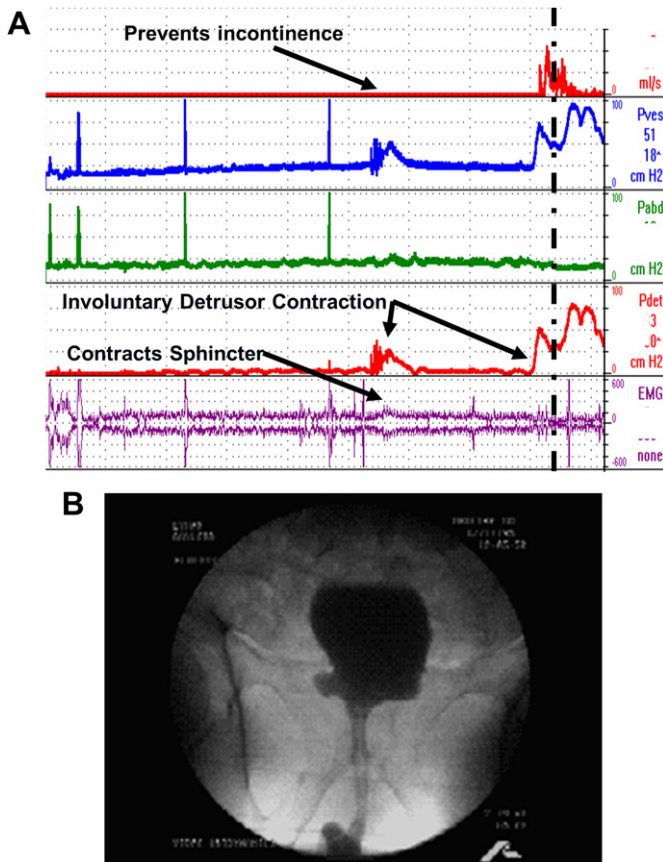


Fig. 3. Type 2 overactive bladder (OAB). Urodynamic tracing in a 69-year-old man who complained of OAB and voiding symptoms AUA symptom score = 22. A digital rectal exam revealed a 20 g, smooth, symmetrical, benign-feeling prostate, and a neuro-urological exam was normal. Uroflowmetry showed a flow of 29 mL/s, a voided volume of 175 mL and a post-void residual (PVR) of 0 mL. A. At a bladder volume of 281 mL, he had an involuntary detrusor contraction, but was able to contract his sphincter, prevent incontinence, or abort the detrusor contraction. These are all good prognostic signs for a successful outcome after behavioral modification. B. X-ray obtained at Qmax showing a wide-open urethra.

obtained first, and if further testing is deemed necessary, multichannel or videourodynamics is done.

2.1. Uroflowmetry

Uroflowmetry can be accurately measured by a variety of electronic flow meters and is expressed in mL/s. The study should be performed when the patient experiences a normal desire to void. A minimum voided volume of 150 mL provides an accurate study. A maximum urinary flow (Q_{max}) of > 15 mL/s is considered normal, < 10 mL/s is abnormal, and $10 \sim 15$ mL/s is equivocal.⁹ The most useful information obtained includes the Q_{max} , flow pattern, voided volume, and shape of the curve. After voiding, PVR is recorded with ultrasound or catheterization if invasive urodynamics follows.

For practical purposes, normal flow excludes clinically relevant BOO, but low flow can be due to BOO, IDC, or simply voiding too small of a volume. Unfortunately, there are no characteristics of the flow curve that can distinguish BOO from IDC; this distinction can only be made by a pressure-flow study (PFS).¹⁰ Despite these limitations, uroflowmetry remains a useful screening test in the initial evaluation of men with LUTS. Both the American Urological Association (AUA) and European Association of Urology Guidelines on BPH recommend uroflowmetry as an optional test in men with moderate/severe symptoms, and it is considered mandatory prior to surgical intervention.¹¹

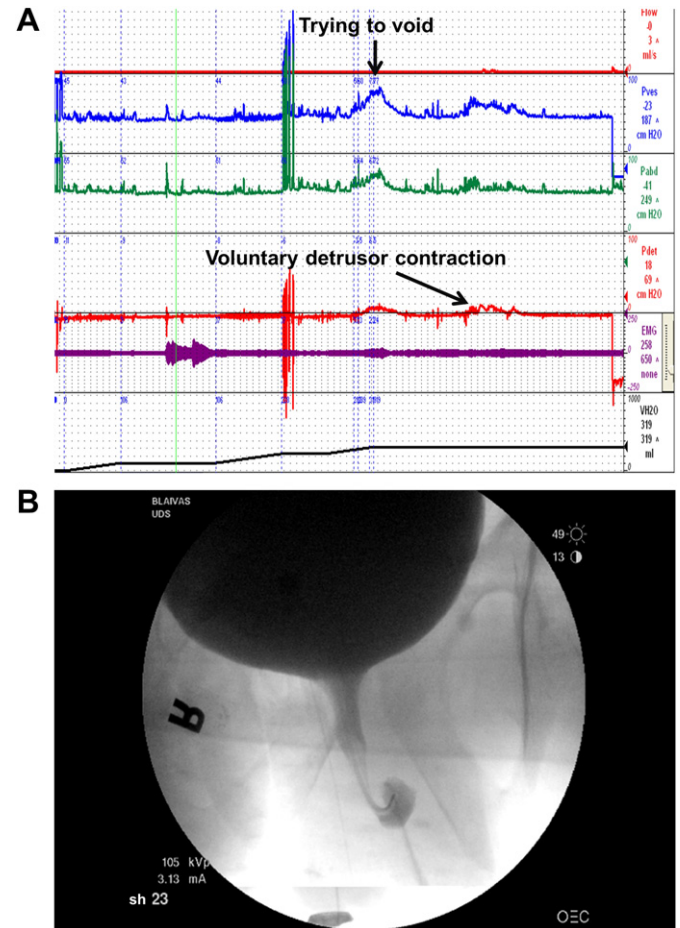


Fig. 4. Impaired detrusor contractility. This 50-year-old man had a 2-year history of overactive bladder (OAB) symptoms. The exam was unremarkable except for an absence of the bulbocavernosus reflex. A prior urodynamic study 1 year previously had shown detrusor overactivity, and he was started on anticholinergics without success. He developed urinary retention that was treated with intermittent catheterization, and this urodynamic study was done about 3 months later. A. Urodynamic tracing. The bladder capacity was 319 mL. He initially tried to void by straining but was unsuccessful. He then voided with a very weak, poorly sustained detrusor contraction. $P_{det}@Q_{max} = 10$ cmH₂O; $Q_{max} = 1$ mL/s. The detrusor contraction only lasted about 20 s. B. X-ray exposed at Qmax showing a wide-open prostatic urethra with some narrowing in the membranous region. Empiric transurethral resection of the prostate on a patient like this is very unlikely to be effective because of the short-lived, weak detrusor contraction and the open urethra on the voiding cystourethrogram as seen in 4B. He remains on intermittent self-catheterization.

2.2. Cystometry

Cystometry records the relationship between detrusor pressure and bladder volume during bladder filling as well as bladder sensations, awareness of involuntary detrusor contractions, and the ability to suppress them. It is the only method that can detect DO, SU, and LBC. In men, it is not useful as a stand-alone procedure. Rather, the AUA guidelines recommend that cystometry be done as part of the PFS. DO is present in about one-half to two-thirds of men with LUTS. In men with BOO, DO, and OAB, symptoms resolve in the great majority after transurethral resection of the prostate (TURP).^{12,13}

2.3. Multichannel urodynamics and videourodynamics

The synchronous measurement and display of multiple urodynamic parameters with radiographic visualization of the LUT (videourodynamics) is the most precise diagnostic tool for

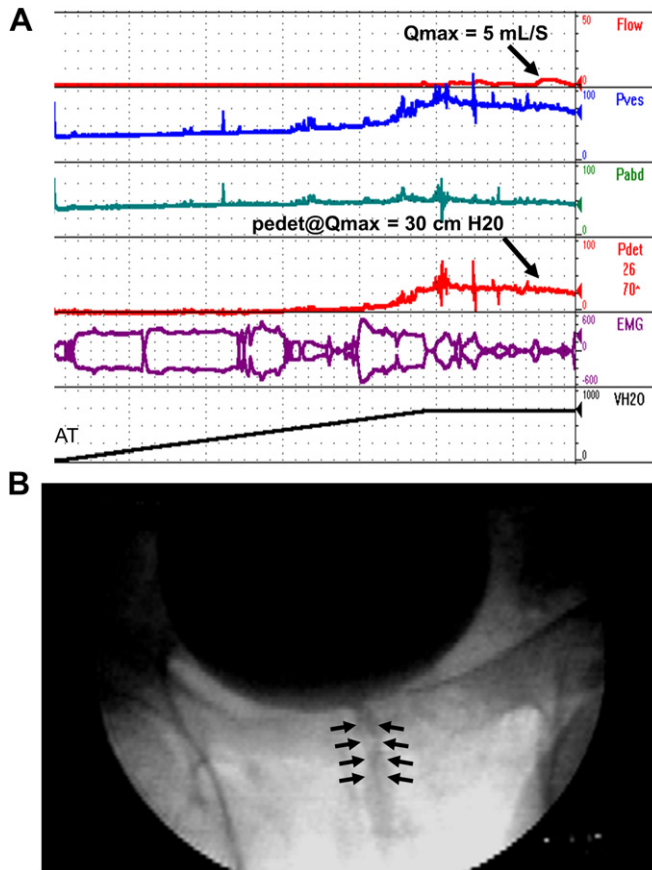


Fig. 5. Impaired detrusor contractility in a 58-year-old man who complained of urinary frequency, urgency, occasional urge incontinence, hesitancy, and a weak stream. A. Urodynamic study: first sensation of filling (FSF) = 272 mL; first urge = 491 mL; severe urge = 620 mL; bladder capacity = 710 mL; Q_{\max} = 6 mL/s; $P_{\det@Q_{\max}}$ = 28 cmH₂O; $p_{\det\max}$ = 41 cmH₂O; bladder outlet obstruction index = 16; Schaefer grade 1, W. Although results of this study fall far short of qualifying as urethral obstruction based on urodynamic criteria, the fact that he had a sustained detrusor contraction and diffuse narrowing of the prostatic urethra suggests prostatic obstruction as well as impaired detrusor contractility. B. X-ray obtained at Q_{\max} showing a narrowed prostatic urethra (arrows). This patient underwent transurethral resection of the prostate and had a very successful outcome.

evaluating LUTS. During videourodynamics, radiographic contrast is used as the infusant for cystometry. By measuring multiple urodynamic variables (Q , vesical pressure (pves), abdominal pressure (pabd), detrusor pressure at maximum flow (pdet), and sphincter EMG), each serves as a check against the other, and one can gain better insights into the underlying pathophysiology. Moreover, since all variables are simultaneously visualized, one can better appreciate their interrelationships and identify artifacts. The International Continence Society recommends standards for the performance of these studies.^{14,15}

3. Urodynamic techniques

A double-lumen urodynamic catheter is passed into the bladder, and a rectal catheter is placed in the rectum to respectively measure vesical and abdominal pressures. The pressure transducers are zeroed to atmospheric pressure at the level of the symphysis pubis. pves and pabd are displayed, and pdet is electronically calculated by subtracting pabd from pves, and displayed on a third channel. Other channels display the sphincter EMG, infused bladder volume, voided volume, and uroflow. For videourodynamics, fluoroscopic images are periodically sampled during filling and voiding.

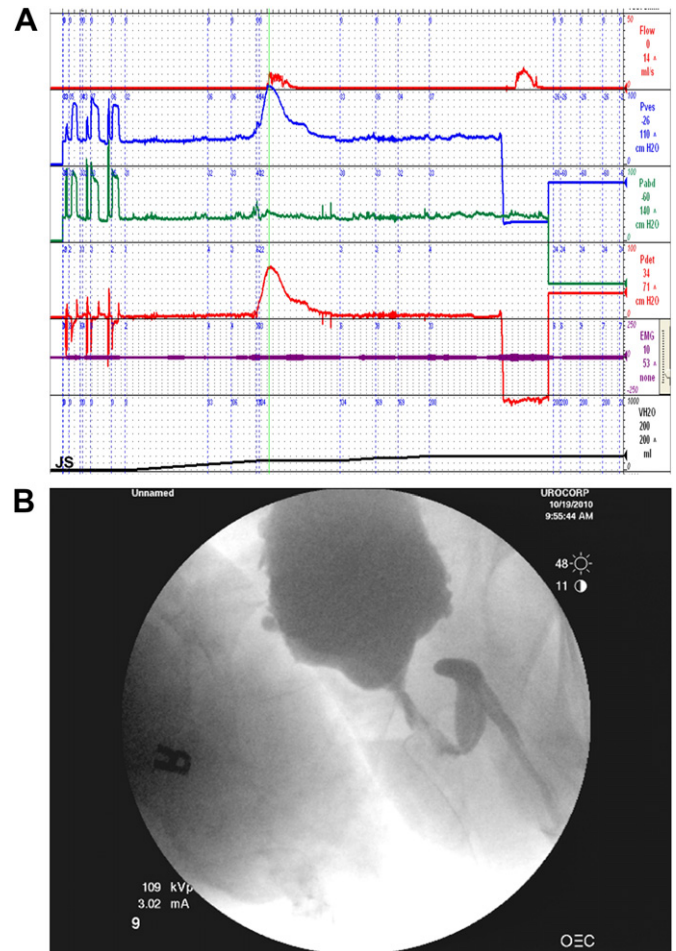


Fig. 6. Overestimation of bladder outlet obstruction (BOO). A 65-year-old man with severe overactive bladder (OAB) symptoms. He underwent KTP laser ablation of the prostate and transurethral resection of the prostate (TURP), but his symptoms persisted. Cystoscopy showed considerable trilobar enlargement and moderate intra-prostatic protrusion with some signs of prior resection/ablation. There were also some inflammatory-looking polypoid lesions in the prostatic urethra. The bladder mucosa had multiple areas of flat erythema, but a biopsy showed only inflammation. A. Urodynamic tracing. $P_{\det@Q_{\max}}$ = 105 cmH₂O; Q_{\max} = 10 mL/s; BOOI index (BOOI) = 105 - 20 = 80; Schaefer grade 5 obstruction. Unintubated Q = 15 mL/s (at the conclusion of the urodynamic study). B. X-ray obtained at Q_{\max} showing a wide-open proximal prostatic urethra, some narrowing of the distal prostatic and membranous urethra, and a normal distal urethra. Despite the elevated BOOI, the presence of the normal unintubated flow mitigated against a diagnosis of BOO, and a third prostate ablating surgery might not be successful.

During bladder filling, vesical sensations and the presence or absence of DO are noted, and bladder compliance is measured. If DO is documented, the patient's awareness, concern, and ability to contract the sphincter, abort the stream, and prevent incontinence are noted. These characteristics are used to classify the type of overactive bladder (OAB).¹⁶

Bladder outlet obstruction (BOO) is defined by PFS parameters. The BOOI index (BOOI) is used to measure the degree of obstruction ($BOOI = P_{\det@Q_{\max}} - 2Q_{\max}$). $P_{\det@Q_{\max}}$ is the detrusor pressure at maximum flow. Men are classified as being obstructed ($BOOI > 40$), equivocally obstructed ($20 < BOOI < 40$), or unobstructed ($BOOI < 20$). Multiple nomograms were described to interpret PFS.^{9,17,18} These plot detrusor pressure (at maximum flow) versus the maximum flow rate and then divide the results into unobstructed, obstructed, and equivocal categories. We prefer the Schaefer nomogram because it provides a simple 6-point obstruction scale and an assessment of detrusor strength.¹⁴

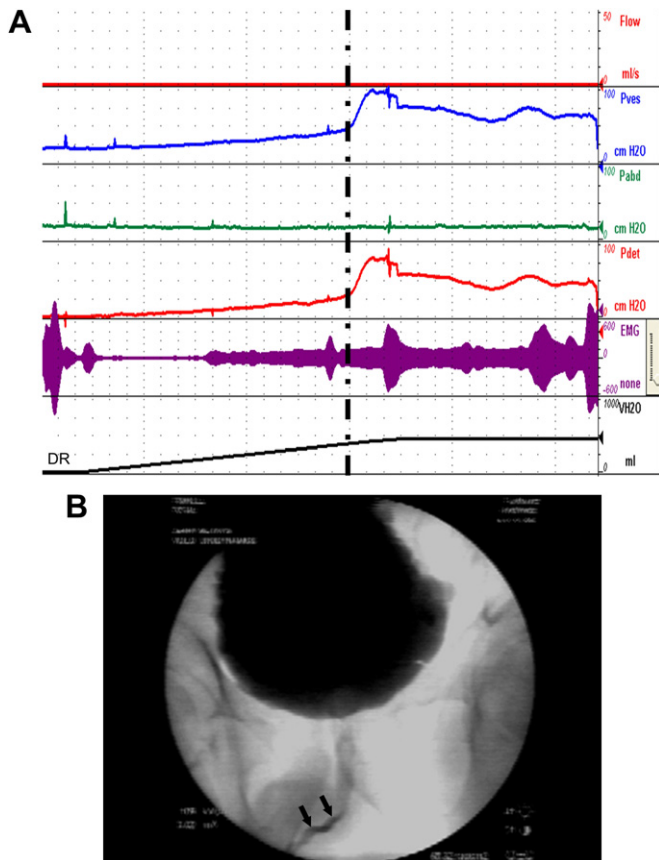


Fig. 7. Low bladder compliance due to longstanding Schafer grade 5 prostatic obstruction. This 57-year-old man was referred because of “voiding dysfunction” of at least 20 years duration. He had been treated with a variety of alpha adrenergic antagonists with no effect. Multiple bladder diaries showed a maximum voided volume = 180 mL, and 24-h volumes ranging 1200–1500 mL. Q_{\max} = 3 mL/s; post-void residual = 350 mL. A. Urodynamic tracing. At bladder capacity, he had a voluntary detrusor contraction and a flow rate too low to activate the flowmeter. $P_{\det}@Q_{\max}$ = 73 cmH₂O; Q_{\max} = 0.5 mL/s. bladder outlet obstruction index = 72. Bladder compliance measured just prior to the detrusor contraction (vertical line) = $375/32 = 11.7$ mL/cmH₂O. B. X-ray obtained at detrusor pressure at maximum flow ($P_{\det\max}$) showing no visualization of the prostatic urethra and a trabeculated bladder. There are shadows overlying the prostatic urethra that might be misinterpreted as contrast but are due to the compound effects of visualization of the penis and pubis. There is some dye in the bulbar and anterior urethra (arrows). The bladder has a scalloped appearance due to marked bladder trabeculations. He underwent transurethral resection of the prostate and had a successful outcome. Subsequent urodynamic study documented resolution of both the low bladder compliance and urethral obstruction.

3.1. Cystoscopy

Despite its widespread use, cystoscopy has a limited role in evaluating the cause of LUTS in men. The cystoscopic appearance of the bladder and urethra are not diagnostic except in the case of urethral stricture and of course, in detecting bladder cancer. Nevertheless, the cystoscopic appearance of the prostate is important in planning surgical procedures, and the presence of trabeculations and bladder diverticula also has clinical import. AUA guidelines recommend cystoscopy in those patients for whom the appearance of the prostate aids in the choice of surgical treatment.¹⁹ We also recommend it for those with refractory OAB.

4. Indications for a urodynamic evaluation

In our judgment, indications for urodynamics in men with LUTS depend upon the threshold of the clinician for obtaining the most accurate diagnostic information, because a determination of the

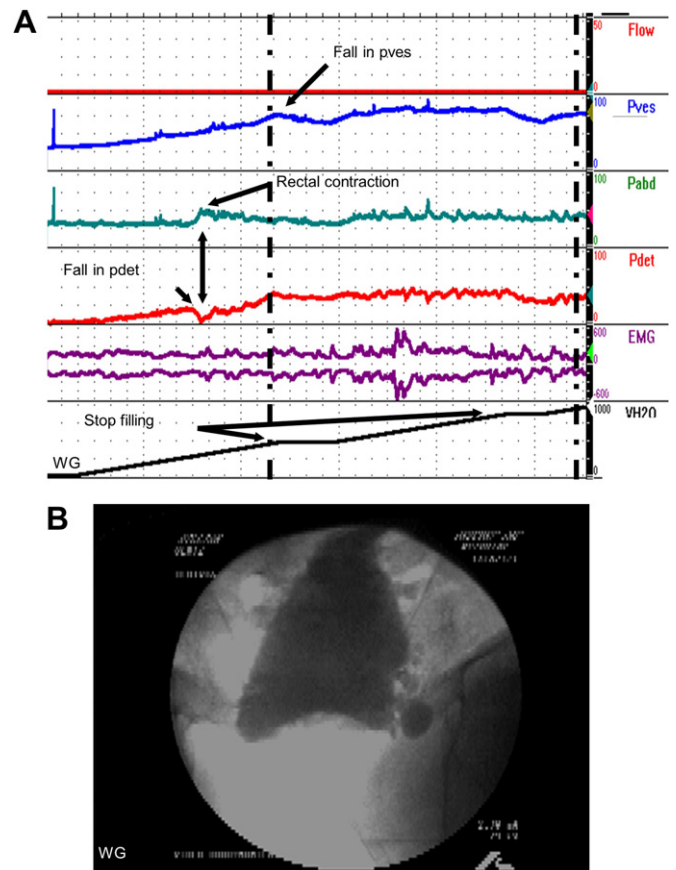


Fig. 8. Low bladder compliance in an 86-year-old man with a long history of lower urinary tract symptoms (LUTS) treated empirically with alpha adrenergic blockade. Upon referral, he had a palpable bladder and was catheterized for over 2.5 L and taught intermittent self-catheterization. Renal and bladder ultrasound showed bilateral hydronephrosis and a huge bladder. A. During bladder filling, there was a steep rise in detrusor and vesical pressures, but a rectal contraction caused an artifactual fall in the detrusor pressure (arrow). At the first vertical line on the left, bladder filling was discontinued because it looked like the patient might be experiencing a detrusor contraction. There was an immediate fall in vesical and detrusor pressures proving that the rise in pressure was due to low compliance and not a detrusor contraction. Bladder compliance = $500/45 = 11$ mL/cmH₂O at the vertical line, but $975/40 = 24$ mL/cmH₂O at bladder capacity (second vertical line on the right). He was unable to void during the study. B. X-ray obtained during filling shows a prostatic impression on the bladder base, multiple medium and small-sized bladder diverticula and a heavily trabeculated bladder. He was treated with intermittent catheterization and his hydronephrosis completely resolved within 1 month. He then underwent transurethral resection of the prostate (TURP) and had a successful outcome. It is our (unpublished) experience that men with longstanding obstruction and low bladder compliance, even in the absence of a detrusor contraction during urodynamics, fare well after TURP.

underlying pathophysiology can only be made with urodynamics. Cystometry is the only method by which bladder sensations and control can be evaluated,¹⁶ and a pressure-flow study is the only proven method of diagnosing BOO.¹⁰ Numerous studies have demonstrated that those with proven obstruction benefit more from a prostatectomy than those who are not obstructed or have impaired detrusor contractility.^{20–28} Nonetheless, from a clinical viewpoint, videourodynamics serve no purpose unless the clinician bases his/her therapy on the results of the study.

Current AUA guidelines on managing BPH recommend PFS as an optional diagnostic test for patients with moderate/severe symptoms (AUASS/IPSS ≥ 8) who choose invasive therapy,¹⁹ and the International Scientific Committee (ISC) of the Fifth International Consultation of BPH regards PFS as an optional diagnostic test,²⁹ but recommends it before invasive therapy or when a precise diagnosis of BOO is important.

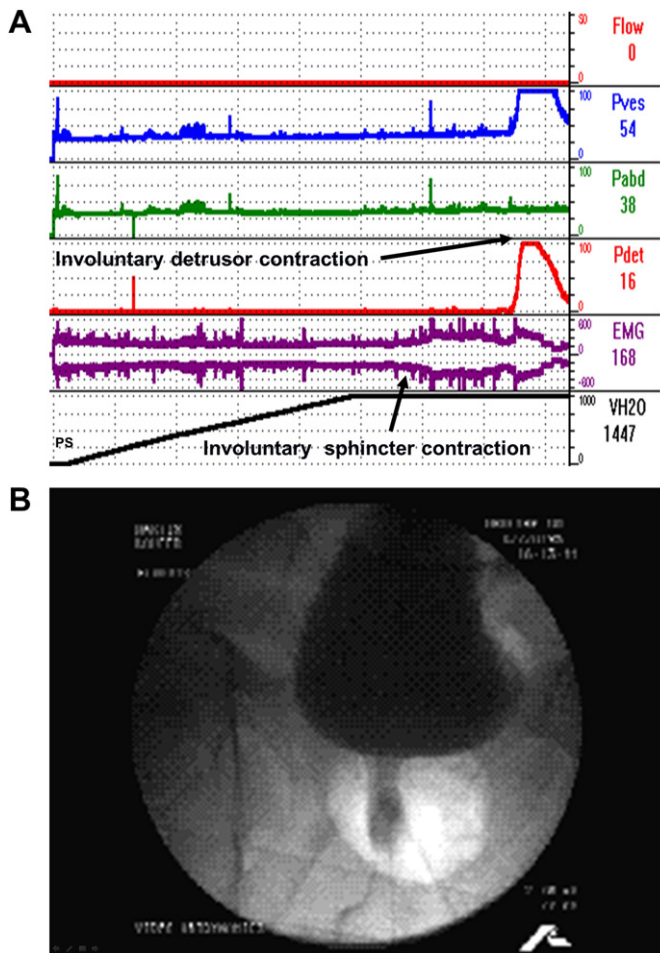


Fig. 9. Detrusor-external sphincter dyssynergia (DESD). A. Urodynamic study demonstrating classic findings of DESD. An involuntary sphincter contraction precedes and continues throughout most of the involuntary detrusor contraction. B. X-ray obtained at the height of the detrusor contraction showing complete obstruction at the membranous urethra due to the sphincter contraction. Transurethral resection of the prostate is of no help in such a patient. Optimal treatment is aimed at abolishing the involuntary detrusor contractions and instituting intermittent self-catheterization.

Our approach slightly differs. We recommend empiric therapy with alpha-adrenergic antagonists for all patients whose symptoms are bothersome enough to warrant treatment and reserve urodynamics for the following indications:

- 1) Failure of empiric therapy;³⁰
- 2) When invasive therapy is being considered;^{31,32}
- 3) In patients with neurologic conditions who are willing to do intermittent self-catheterization as part of a treatment program;
- 4) In men with very low flow rates or elevated PVR's, we obtain renal ultrasound and if hydronephrosis is found, we recommend urodynamics; and
- 5) In men who have undergone major pelvic surgery or had prior pelvic radiation.

For about a decade, though, we routinely performed video-urodynamics in men whose LUTS were bad enough to warrant treatment based on bother alone, and the lessons we learned from that experience are invaluable. Here are some of the things we learned.

- 1) From a urodynamic perspective, the pathophysiology of symptoms is multifactorial in most men (Tables 1 A,B).

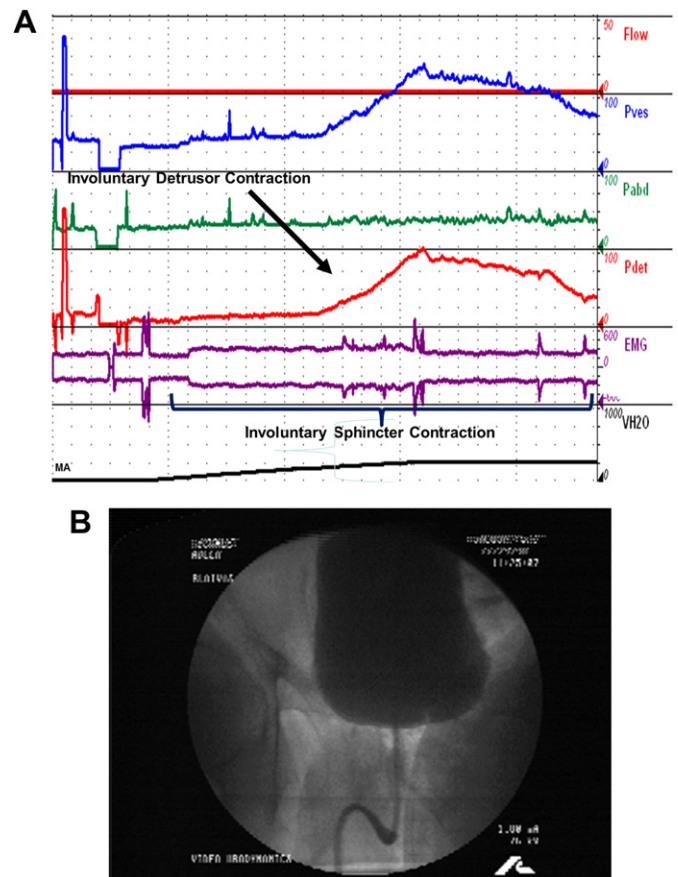


Fig. 10. Detrusor-external sphincter dyssynergia (DESD) and prostatic urethral obstruction in a 52-year-old man who presented with a 2-year history of lower urinary tract symptoms. A. Urodynamic study. An involuntary detrusor contraction occurred at a bladder volume of 264 mL. It was preceded by a long increase in electromyographic activity that continued throughout the detrusor contraction. $Q_{max} = 0.7$ mL/s, $P_{det}@Q_{max} = 92$ cmH₂O. B. X-ray obtained at detrusor pressure at maximum flow ($p_{det-max}$) demonstrating some contrast in the bulbar urethra, but none at all in the prostatomembranous urethra. It is impossible from this study to determine to what degree the patient's symptoms are due to prostatic obstruction versus DESD. Depending on the patient's preferences, transurethral resection of the prostate could be considered and might alleviate his symptoms, but there is a high risk that his overactive bladder symptoms would persist.

- 2) Regardless of the symptoms, when there is severe prostatic obstruction, TURP has a very high success rate (well over 90%), even when symptoms are primarily storage symptoms and even when there is detrusor overactivity.^{13,20–22,33} (Figs. 1,2).
- 3) Men with overactive bladder symptoms who do not have urethral obstruction (Fig. 3) are not helped by prostate surgery and may even get worse,^{23,24} but they sometimes improve on alpha-adrenergic blockade alone. Anticholinergics may also be effective as combination therapy with both classes of drug.
- 4) The success rate of TURP in men with mild obstruction and OAB symptoms is considerably less than those with severe obstruction.^{21,25,26} In these patients, the indications for TURP are not well established. As a general rule, the worse the BOO is, the more likely that the OAB symptoms will resolve and vice versa, so treatment is largely empirical.
- 5) Overall, men with impaired detrusor contractility do not fare as well after TURP as those with obstruction (Fig. 4).^{26–28}
- 6) However, in some men it is possible to deduce obstruction even when the pressure flow study does not qualify based on the

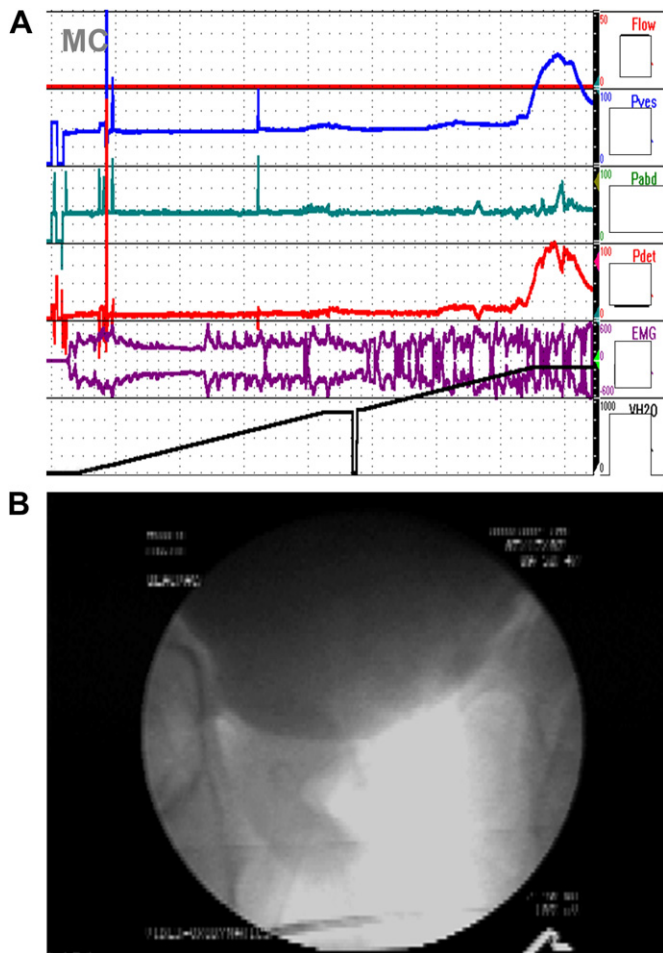


Fig. 11. Large capacity bladder and bladder neck obstruction. A 31-year-old man had been treated with intermittent catheterization for 2 years because of urinary retention that was thought to be due to a neurogenic bladder. His initial urodynamic study was thought to demonstrate detrusor areflexia because there was no bladder contraction up to a volume of 1200 mL at which time the examination was discontinued. A. Urodynamic study. During this study, the bladder was filled until he felt comfortably full (1450 mL) and when asked to void, he had a sustained detrusor contraction to 105 cmH₂O, but he was still unable to void. B. X-ray exposed during the detrusor contraction showing complete obstruction at the bladder neck. He underwent transurethral resection of the prostate and voided normally thereafter, but his creatinine remained unchanged.

BOOI or the nomograms (Fig. 5). The difference between the two videourodynamic studies depicted in Figs. 4 and 5 is that in the former, the detrusor contraction is very short lived and of low magnitude, and the urethra looks unobstructed on the voiding cystourethrogram; whereas, in the latter, there is a sustained detrusor contraction of higher magnitude, and the entire prostatic urethra is narrowed on the x-ray. The latter patient had a successful outcome after TURP; the former remains on intermittent self-catheterization.

- 7) Indices of bladder outlet obstruction (the BOOI and nomograms) may overestimate obstruction, but do not underestimate it (Fig. 6).
- 8) Longstanding BOO can cause LBC which is reversible after TURP (Fig. 7), and in some cases, the LBC is the only finding (Fig. 8). In the latter patients, TURP is usually effective even though BOO was not definitively diagnosed.
- 9) In men with neurogenic disorders such as spinal cord injury, Parkinson's disease, spina bifida, and multiple sclerosis, urodynamics is strongly indicated in most, but not all patients (Fig. 9). The only exceptions are men for whom intermittent

catheterization or surgical treatment is not being considered. Those patients may be managed without urodynamics, but renal and bladder ultrasonography (USG) should periodically be performed to ensure that there is neither bladder nor renal deterioration.

- 10) Occasionally, urodynamics will disclose an unexpected neurologic disorder manifesting as detrusor external sphincter dys-synergia, which requires specific treatment (Fig. 10).
- 11) In men with voiding difficulty or urinary retention, it is important to fill the bladder until a detrusor contraction occurs or until a strong urge to void or an uncomfortable fullness is felt (Fig. 11). Failure to do so might underdiagnose BOO by as much as one-third, and a misdiagnosis of acontractile detrusor will be made.³⁴

Conflicts of interest statement

Johnson F. Tsui declares that he has no financial or non-financial conflicts of interest related to the subject matter or materials discussed in the manuscript. Jerry G. Blaivas is an investor in Endogun and a consultant for Pfizer and Merck.

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